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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,562	09/26/2001	F. Michael Shofner II	SEA-6-7-US-C	4670
31671	7590	07/29/2003		
STEVEN C. SCHNEDLER CARTER & SCHNEDLER, PA 56 CENTRAL AVE., SUITE 101 PO BOX 2985 ASHEVILLE, NC 28802			EXAMINER DAWSON, GLENN K	
			ART UNIT 3761	PAPER NUMBER

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/966,562	SHOFNER ET AL.
	Examiner Glenn K Dawson	Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06 May 2003.

2a) This action is FINAL.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 10 and 11 is/are allowed.

6) Claim(s) 1-9 and 12-21 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9 line 7, there is no antecedent basis for "said mixing chamber".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,3-9,12 and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerde-'512.

Gerde discloses several embodiments of powder inhalers wherein a metering chamber 12 receives an amount of powder, a jet 18 of gas fluidizes the powder and a mixing chamber 22(or portion thereabove) for allowing the aerosol generated to expand into a bolus for breathing by a patient.

Claims 1 and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Century-5570686.

Century discloses a metering chamber 114 which is filled with powder, and fluidized by a gas jet produced by either a syringe, pulsatile air source, or compressed gas container. The bolus produced enters a chamber downstream of valve 21 and thereafter exits tube 122 to the patient.

Claims 1,5,8,18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Minnesota Mining-EP 0 826 386 A2.

Minnesota Mining discloses a powder inhaler having a metering chamber 32, a gas jet 23 and a mixing chamber 16 and outlet 18.

Claims 1,4-6,8 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Barrington, et al.-4184258.

Barrington discloses a device having a metering chamber 24 filed with powder, a gas jet 28-30 for fluidizing the powder and a mixing chamber 25 and outlet 26.

Claims 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Blaha-Schnabel-5596982.

Blaha-Schnabel discloses a device a solution of drug and solvent is aerosolized by a gas jet and allowed to expand into a bolus which is caused to dry to form a solute residue (powder). See col. 1 lines 20-37; col. 3 lines 5-20.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Century-'686 or Minnesota Mining-'386.

Century and Minnesota Mining disclose the invention as claimed with the exception of the specific size of the metering chamber. Century discloses that it was known to vary the size of the chamber... Minnesota Mining discloses a chamber having a volume of .24 mm<sup>3</sup>.

It would have been obvious to have provided the chambers of Century or Minnesota Mining within the claimed parameters as merely an obvious design choice given that it was known to deliver extremely small quantities of powder to patients depending on the particular ailment and size or age of the patient. See *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).

***Allowable Subject Matter***

Claims 10 and 11 are allowed.

***Response to Arguments***

Applicant's arguments filed 05-06-03 have been fully considered but they are not persuasive.

Gerde's chamber is a metering chamber in that powder is metered either by being placed in sealed cups-see col. 9 lines 12-19, or metered through the use of a dowel cup 56 see col. 9 lines 28-39.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Glenn K Dawson  
Primary Examiner  
Art Unit 3761

gkd  
July 23, 2003